K022024/P

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1.2 510(k) Summary

Sierra BioSearch, Inc.
395 Mt. Tom Road
Bishop, California 93514

510(k) Summary of Safety and Effectiveness

Identification of the Device

Proprietary-Trade Name:	MT Alert Infusion Monitor
Classification Name:	Monitor, Electric for Gravity Flow Infusion Systems
Device Class:	II
Product Code:	FLN
Common/Generic Name:	Gravity Infusion Monitor

Equivalent Predicate Devices

The MT Alert Infusion Monitor is substantially equivalent in design and function to the Smith & Nephew Dyonics LeveLert System.

Indications for Use

MT Alert Infusion Monitor is intended for use in any healthcare setting where gravity-flow infusions are utilized.

Description of the Device

The MT Alert Infusion Monitor is a passive weighing device that alarms when the infusion bag is near-empty. The alarm point can be set by the user. In addition, MT Alert may also assist in monitoring fluid bolus administration. MT Alert will alarm when a prescribed bolus of fluid has been taken from the infusion bag. MT Alert provides various audio and visual alarms. MT Alert operates from common alkaline batteries and mounts on common poles and rods.

Safety and Effectiveness in Comparison to Predicate Devices.

The validation procedures performed on the system indicate that the new device is as safe and effective as the predicate devices.

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Substantial Equivalence Chart

Feature	***MT Alert™***	***LeveLert***
Used for monitoring the fluid level of an infusion bag.	Yes	Yes
Automatic alarm when the fluid level has reached a pre-determined weight with audio and visual alarms.	Yes	Yes
Adjustable near-empty alarm point.	Yes- Easily programmed by hanging the desired weight.	Yes.
Accommodates most typical infusion bag sizes.	Yes (up to 3 liter size)	Yes (up to 3 liter size)
Bolus monitoring feature.	Yes (1 liter mode only)	No.
Passive device, no fluid control functions.	Yes	Yes
Infusion Container hangar.	Yes	Yes
Pole Mounting.	Yes	Yes
Power	2- AA batteries, typical 180 day life	Powered externally
Device Class.	Class II	Class II

Richard Citrenbaum, MD, President

K013121
(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Stryker Endoscopy
Michael Hilldoerfer
5900 Optical Court
San Jose, California 95138

Re: K022248
Trade Name: Stryker L3 Hydroalert
Regulation Number: 880.2420
Regulation Name: Electronic Monitor for gravity flow infusion system
Regulatory Class: II
Product Code: FLN
Dated: July 10, 2002
Received: July 12, 2002

Dear Mr. Hilldoerfer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

July 10, 2002

510(k) Number if known: K022248

INDICATION FOR USE:

The Stryker L3 Hydrolert is intended to monitor irrigant levels primarily during arthroscopic procedures and to alert operating room personnel of a low irrigant fluid level condition. It will offer both increased efficiency in arthroscopic procedures and universal compatibility with both arthroscopic pump and gravity fluid management systems. It is intended for use with saline solution or any other standard irrigant. It is not intended for use as an intravenous infusion monitor. The alarm is designed to be reusable.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022248

Prescription Use ✓ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)